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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,117	10/13/2005	Francois-Xavier Berthet	B45315	8407

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EXAMINER
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NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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03/13/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/523,117	<b>Applicant(s)</b> BERTHET ET AL.	
	<b>Examiner</b> Mark Navarro	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17, 19-22, 25-65, 69-80 and 82-115 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15, 17, 20, 22, 45, 50-52, 54-61, 82, 83, 85-88, 90, 93, 95, 96, 98, 103, 114 and 115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12,16,19,21,25-44,46-49,53,62-65,69-80,84,89,91,92,94,97-102 and 104-113.

### **DETAILED ACTION**

Applicants amendment filed December 2, 2008 has been received and entered. Claims 18, 23-24, 66-68 and 81 have been cancelled. Accordingly, claims 1-17, 19-22, 25-65, 69-80, 82-115 are pending in the instant application. of which claims 12, 16, 19, 21, 25-44, 46-49, 53, 62-65, 69-80, 84, 89, 91-92, 94, 97, 99-102, 104-113 have been withdrawn from further consideration as being drawn to a non-elected invention or a non-elected species.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claim 2 for the phrase "preferably" rendering the claim indefinite is withdrawn in view of Applicants amendment.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English

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language.

2. The rejection of claims 1-5, 7-15, 17, 20, 22, 50-52, 54-61, 82, 85, 87, 90, 93, 95, 96, 98, 103, and 114-115 under 35 U.S.C. 102(b) as being anticipated by Peak et al is maintained.

Applicants are asserting that Peak et al relates to proteins comprising conserved amino acids of Nhha polypeptides (page 2, lines 31-32). Applicants assert that Peak does not teach an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial membrane associated protein. Applicants finally assert that the composition of Peak et al does not necessarily contain another Neisserial adhesion, protein, toxin, Fe acquisition protein or membrane associated protein.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that Peak et al relates to proteins comprising conserved amino acids of Nhha polypeptides (page 2, lines 31-32). However, as set forth previously, Nhha = Hsf as set forth on page 12 of Applicants specification, and as can be clearly seen in claim 2 of the instant application, Hsf is a Neisserial autotransporter antigen. Accordingly, the disclosure of Peak et al is deemed to meet the limitation of "at least one Neisserial autotransporter antigen."

Second, Applicants assert that Peak does not teach an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial membrane associated protein. However, Applicants are again directed to Example 2 of Peak et al. Peak et al disclose of overexpressing the Nhha protein in a Neisserial meningitidis strain. This strain is clearly an "immunogenic composition" as it can clearly elicit the production of antibodies. It is also clear that this composition contains "at least one Neisserial autotransporter antigen" as it is being overexpressed by the strain.

Finally, Applicants assert that the composition of Peak et al does not necessarily contain another Neisserial adhesion, protein, toxin, Fe acquisition protein or membrane associated protein. However, as Peak et al used a live Neisserial strain to overexpress the Neisserial autotransporter antigen, this Neisserial strain most certainly contained at least one Neisserial membrane associated protein, given that it is a Neisserial strain with an intact membrane.

The claims are drawn to an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial madhesion associated protein.

Peak et al (WO 2001/055182) disclose of immunogenic compositions comprising Neisserial Nhha. (See claims). Note Nhha = Hsf as set forth on page 12 of Applicants specification). Peak et al further disclose of overexpressing the Nhha protein in a Neisserial meningitidis strain. (See Example 2).

Given that the immunogenic composition disclosed by Peak et al comprised an overexpression of Nhha/Hsf, and that it was inherently in the presence of other Neisserial adhesion proteins or toxins or Fe acquisition proteins or membrane associated proteins, the disclosure of Peak et al is deemed to anticipate the instantly filed claims.

3. The rejection of claim 1 under 35 U.S.C. 102(e) as being anticipated by US Publication 2005/232936 is withdrawn in view of Applicants arguments.

4. The rejection of claims 1-15, 17, 20, 22, 50-52, 54-61, 82-83, 85-87, 90, 93, 95, 96, 98, 103, and 114-115 under 35 U.S.C. 102(e) as being anticipated by US Publication 2003/0215469 is maintained.

Applicants are asserting that Hsf is not disclosed in the priority documents claimed by US Publication 2003/0215469, and therefore, the Hsf subject matter is entitled to the filing date of the continuation-in-part December 17, 2002.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants assertion that US Publication 2003/0215469 does not disclose Hsf in

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its priority documents is correct. However, the filing date of the continuation-in-part application, December 17, 2002, is 7 months prior to Applicants instant US filing date of July 31, 2003. It is noted that Applicants have claimed benefit of 12 foreign applications, however the Examiner has been unable to find support for the instantly claimed combination of at least one Neisserial autotransporter antigen and at least one Neisserial adhesion, Neisserial toxin, Neisserial Fe acquisition protein or Neisserial membrane associated protein in any of the 12 foreign documents which would support this generic claim prior to the December 17, 2002 date of US Publication 2003/0215469. Applicants may be able to overcome this rejection by pointing to support (page and line number) of the limitations for each rejected claim in any foreign priority document with a filing date prior to December 17, 2002.

The claim is drawn to an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial madhesion associated protein.

US Publication 2003/0215469 discloses of an immunogenic composition comprising an outer membrane vesicle and an autotransporter antigen, Hsf. (See claim 8).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The rejection of claims 1-15, 17, 20, 22, 45, 50-52, 54-61, 82, 83, 85-88, 90, 93, 95, 96, 98, 103, and 114-115 under 35 U.S.C. 103(a) as being unpatentable over US Publication 2003/0215469 or Peak et al in view of US Publication 2007/087018 is maintained.

Applicants are asserting that the Hsf subject matter is US Publication 2003/0215469 is not prior art. Applicants further assert that Peak has not taught of

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“immunogenic compositions comprising both an autotransporter (Hsf) and various other Neisserial antigens.” Applicants finally assert that the Examiner has not provided any support for the conclusion that including OMP 85 in a Neisseria immunogenic composition for eliciting an immunogenic response would be obvious.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the Hsf subject matter is US Publication 2003/0215469 is not prior art and that Peak has not taught of “immunogenic compositions comprising both an autotransporter (Hsf) and various other Neisserial antigens.” However, both of these arguments have been fully addressed above.

Finally, Applicants assert that the Examiner has not provided any support for the conclusion that including OMP 85 in a Neisseria immunogenic composition for eliciting an immunogenic response would be obvious. However, Applicants are again directed to US Publication 2003/0215469 which sets forth that “**OMP85 proteins** of *N. gonnorrhoeae* and *N. meningitidis* are **useful in vaccine compositions, thereapeutic compositions** and diagnostic compositions. (Emphasis added, see abstract again). It is proper to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007). See also *id.* At 1742, 82 USPQ2d 1397 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

The claim is drawn to an immunogenic composition comprising at least one

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Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial adhesion associated protein, wherein OMP 85 is upregulated.

The teachings of US Publication 2003/0215469 and Peak et al are set forth above.

Neither US Publication 2003/0215469 nor Peak et al teach of upregulating OMP 85.

US Publication 2007/087018 teach of immunogenic compositions for eliciting protective immune responses which comprise *Neisseria gonorrhoeae* and *N. meningitidis* OMP 85. (See abstract).

Given that 1) US Publication 2003/0215469 and Peak et al have taught of immunogenic compositions comprising both an autotransporter (Hsf) and various other Neisserial antigens, and that 2) US Publication 2007/087018 has taught of the desire for including OMP 85 in *Neisseria* immunogenic compositions for eliciting an immunogenic response, it would have been prima facie obvious to one of ordinary skill in the art to combine the OMP 85 as taught by '018 with the composition taught by '469 or Peak et al.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/  
Primary Examiner, Art Unit 1645  
March 10, 2009